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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,272	12/09/2003	Laval Chan Chun Kong	VIRO-5	2563

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,272	CHAN CHUN KONG ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26,33,35,38-42,45-47 and 50-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26,33,35,38-42,45-47 and 50-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of group II in the reply filed on May 30, 2006 is acknowledged. The traversal is on the ground that the Markush elements have unity of invention. In view of the prior art of US 6,881,741 which evidenced that the Markush elements were examined together. The restriction is hereby withdrawn.

Claims 1-24, 27-32, 34, 36-37, 43-49 have been canceled. Claims 25-26, 33, 35, 38-42, 45-47, 50-101 are pending.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 50, 52-56, 58, 59, 25, 26, 35, 42, 45-47, 64-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Chan Chun Kong et al. US 6,881,741.

See col. 367-368 compound 573, 574, col. 369-370 compound 579 and composition and method of using as claimed in claim 77-83.

The mere fact that the reference patent shows but does not claim certain subject matter and the application which claims it are owned by the same assignee does not avoid the necessity of filing an affidavit or declaration under CFR 1.131, that the patentee derived the subject matter relied on from the applicant (MPEP §716.10).

A showing that the inventions were commonly owned or subject to an obligation of assignment to the same person, at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) or be sufficient to overcome such a rejection. See MPEP §706.02(l), §706.02(l)(1).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-26, 33, 35, 38-42, 45-47, 50-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan Chun Kong et al. US 6,881,741.

Determination of the scope and content of the prior art (MPEP §2141.01)

Chan chun kong et al. '741 disclosed anticipating species of the instant claims which have been pointed out supra. Generically, the same compounds have been disclosed and exemplified, see '741 claim 1 col. 377-380.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art claims is that the instant are more limited to the narrow combination of the variables disclosed and claimed in the prior art. The prior art have provided ample enabling examples as disclosed in col. 102-378. The different substituents on the cyclohexyl ring have also been explicitly exemplified (see compounds 409, 513) the different rings (see compound 509) have been clearly enabled.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the examples and the generic teaching of the Chan Chun Kong et al. '741 is in possession of the narrower scope of the instant claims which are fully embraced by the generic scope of the prior art. In absence of unexpected results, there is nothing unobvious in picking some among many especially when specific feature of the proven compounds exemplified by the prior art clearly guided one skilled in the art to pick and choose the narrower scope of the instant limitation.

4. Claims 25-26, 33, 35, 38-42, 45-47, 50-101 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-174 of U.S. Patent No. 6,881,741. Although the conflicting claims are not identical, they are not patentably distinct from each other for the same rational as delineated supra for obviousness under 35 USC 103(a) and hereby incorporated by reference.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The filing of an affidavit to overcome the 102(e) or 103(a) rejection does not overcome the necessity of filing a terminal disclaimer in obviating obviousness type double patenting since the issue of obviousness is regarding the claims as well.

5. Claims 25-26, 33, 35, 38-42, 45-47, 50-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what does the term "preventing infection in a host" mean. Please note being a host, it must already have at least one virus being incubated in the individual. Thus, it is impossible for a host to have de novo prevention.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact t+erms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-41 and 61, 63 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to use the invention commensurate in scope with the breadth of the claims.

Claims 40 and 61 are drawn to treating and *preventing* Flaviviridae viral infection in a hose. It is unclear how can a host who must have at least one Flaviviridae being incubated in such individual can be "prevented' of the viral infection. Viral infection in a "host" can be altered by stopping viral spread, change viability of the virus, even killed by the drug, but no evidence in the record can be found that the claimed compound can prevent *infection* in a host.

Claims 41 and 63 are drawn to a method of treating or preventing Flaviviridae viral infection in a host using a compound of claim 50 and at least one addition agent chosen from interfereon α, ribavirin, silybum, marianum, interleukine-12, amantadine, bibozyme, thymosin, N-acetyl cycteine or cyclosporin.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Courts rely on the following factors set out in *In re Wands* to determine whether undue experimentation is required to practice a claimed invention, i.e. whether the claimed invention is enabled:

(a) The breadth of the claims;
(b) The nature of the invention and predictability in the art;
(c) The state of the prior art;

(d) The level of one of ordinary skill;
(e) The existence of working examples; and
(f) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407.

The analysis is applied to the instant case.

(a) The claims are drawn to a method of treating and preventing Flaviviridae viral infection in a host. Not only denovo prevention in a host is self confliction and beyond the skill of person in the art, the specification does not provide a precise definition for how such combination in what dosage or what sequence or site of administration can such treatment or prevention be achieved.

(b) The invention is physiological in nature as it is directed toward pharmaceuticals and treating viral infection for which the state of the art indicated is highly unpredictable. "[T]he scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). In the highly unpredictable pharmaceutical art, the required disclosure is greater than for the disclosure of an invention involving predictable factors such as mechanical or electrical elements. *In re Vaeck*, 20 USPQ 2d 1438 (CAFC 1991).

(c) The state the art is such that combination of one compound with another agent must be evaluated on a individual basis (see CA 142:253391) without any general extrapolation or umbrella effect can be followed. Absent of any specific objective evidence, no prediction can be drawn based on mere naming agents.

(d) The level of skill required to practice the invention is high due to its pharmaceutical nature.

(e) The specification contains no working examples demonstrating the compounds to be combined with any of the agent or its operability in treating and preventing viral infection. (f) The quantity of experimentation necessary to use the disclosed invention is high. Because no indication as to what dosage, site of administration, sequence of administration etc. was

disclosed. The skilled artisan is subject to undue experimentation to determine which combination should be made in what way can such combination be operable .

Based on the limited disclosure, the unpredictability in the art, and the level of skill required to practice the invention, the skilled artisan would be subject to undue experimentation to determine how to use the invention commensurate in scope with the breadth of the instant claims.

7. *Claim Rejections - 35 USC § 112 (Written Description)*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40 and 62 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The invention must be described, "with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection." *University of Rochester v. G.D. Searle & Co., Inc.*, 249 F. Supp. 2d 216 (W.D.N.Y. 2003) *affirmed* 358 F.3d 916 (Fed. Cir. 2004). An adequate written description thus "guards against the inventor's overreaching by later claiming that which he did not invent, by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Vas-Cath v. Mahurkar*, 935 F.2d at 1561 (Fed.Cir. 1991).

The claim is drawn to a method of treating or preventing Flaviviridae viral infection with a compound of claim 50 and a viral serin protease inhibitor, viral polymerase inhibitor, viral helicase inhibitor, immunomodulating agent, antioxidant agent, antibacterial agent, therapeutic vaccine, hepatoprotectant agent or antisense agent. Definitions for each group of "other" agent do not share any commonality in nature. Such agent ranged from enzyme inhibitor to

hepatoprotectant which do not have any relationship with each other in chemical structure or functionality. Therefore, the claim reaches through to future material developed in the individual field which have not yet been known or discovered. This broad protection would give applicants patent protection extending beyond that which is described in the specification, known in the art, or possessed by applicants in violation of 35 U.S.C. §112.

For a more detailed explanation and commentary on reach-through claims, see LeCointe, *Reach-Through Claims*, INTERNATIONAL PHARMACEUTICAL (2002) (also available at: http://www.bakerbotts.com/infocenter/publications/detail.aspx?id=bffe4a7d-5beb-4cf8-a189-15a5f190f0eb) and Silva, *Reach Through Claims: Bust or Boon?*, INTELLECTUAL PROPERTY UPDATE (available at: http://www.dorsey.com/publications/legal_detail.aspx?FlashNavID=pubs_legal&pubid=170565003)

These articles draw their conclusions from *Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004). As the articles point out, claims such as "a method of treating a disease by administering a compound which is an enzyme X agonist," where there is no additional description of such a compound (i.e. chemical formula) is considered a reach-through claim. Applicants' claim is similar in that it is drawn to viral serine protease inhibitor, viral polymerase inhibitor, viral helicase inhibitor, immunomodulating agent, antioxidant agent, antibacterial agnent, therapeutic vaccine, hepatoprotectant agent or antisense agnet there is no additional description of such agents.

Claim Rejections - 35 USC § 112 (Enablement)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40 and 62 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the claimed invention. The claim reaches into future development in the viral serine protease inhibitor, viral polymerase inhibitor, viral helicase inhibitor, immunomodulating agent, antioxidant agent, antibacterial agnent, therapeutic vaccine, hepatoprotectant agent or antisense agent field. The skilled artisan cannot practice a method of treating Flaviviridae viral infection in a host material that has not yet been discovered.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 14, 2006

Celia Chang
Primary Examiner
Art Unit 1625